

outside the State of Georgia, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Georgia.

**LIBELED:** 7-28-61, N. Dist. Ga.

**CHARGE:** 502(b)—while held for sale, the repacked articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f) (1)—their labeling failed to bear adequate directions for use and they were not exempt from that requirement since the articles were subject to the provisions of 503(b) (1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; 503(b) (4)—the articles were subject to the provisions of 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and 502(a)—while held for sale, the sample legend on the unrepacked articles was false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs.

**DISPOSITION:** 9-19-61. Default—destruction.

**6787. Pluraxin vitamin capsules.** (F.D.C. No. 45839. S. No. 61-959 R.)

**QUANTITY:** 36 100-capsule btls. at Wichita, Kans.

**SHIPPED:** Between 11-11-58 and 8-1-60, from New York, N.Y.

**LABEL IN PART:** "Pluraxin High Potency Multiple Vitamin Mixture Therapeutic Stress Formula\* Each Capsule Contains \* \* \* Folic Acid 1.5 mg. \* \* \* Dose: 1 or 2 capsules daily."

**LIBELED:** On or about 7-3-61, Dist. Kans.

**CHARGE:** 502(a)—while held for sale, the label statement "Therapeutic Stress Formula \* \* \* Formula of Food and Nutrition Board, National Research Council, Plus Vitamins A and D," was false and misleading, since it was contrary to fact; and 503(b) (4)—the article was a drug subject to the provisions of 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 10-20-61. Default—destruction.

**6788. Progeri-Lam capsules and Piri-Doxin.** (F.D.C. No. 45892. S. Nos. 32-269 R, 32-271 R.)

**QUANTITY:** 59 30-capsule btls. of *Progeri-Lam capsules* and 139 10-cc. vials of *Piri-Doxin* at Santurce, P.R.

**SHIPPED:** 9-14-60 and 9-19-60, from Oceanside, N.Y., by Lambda Pharmacal Laboratories, Inc.

**LABEL:** (Btl.) "Lambda Progeri-Lam Hormones, Vitamins - Digestive Enzymes, Lipotropic factors, Bioflavonoids, Anti-anemia components, capillary strength factors and proteins Each capsule contains: \* \* \* Lambda Pharmacal Laboratories, Inc. 391 Atlantic Ave., Oceanside, N.Y. \* \* \* By Medical Prescription Only" (vial) "Lambda Piri-Doxin (B Complex). For intramuscular use Dosage: 1 cc daily \* \* \* By medical prescription only Lambda Pharmacal Laboratories, Inc."

**LIBELED:** 5-16-61, Dist. P.R.

**CHARGE:** 503(b)(4)—when shipped, the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 8-3-61. Default—destruction.

**6789. Hy-Jet Wafers, Medcol Cotabs, and Medatinic tablets.** (F.D.C. No. 45895. S. Nos. 31-330 R, 31-332/3 R.)

**QUANTITY:** 17,580 *Hy-Jet Wafers* in btls. of 12 wafers, 24 wafers, and 500 wafers; 50,000 tablets of *Medcol Cotabs* in bulk containers and an undetermined number of 100-tablet btls. of *Medcol Cotabs*; and approximately 20,000 tablets of *Medatinic tablets* in 100-tablet btls., at New Orleans, La., in possession of Medco Co., Inc.

**SHIPPED:** The *Hy-Jet Wafers* were shipped on 2-12-60, from Gardena, Calif., by S. O. Barnes & Son, Inc.; and the other articles were shipped by a different firm, from Memphis, Tenn., on 12-11-59 and 12-28-59.

**LABEL IN PART:** (Btl.) "A New Concept in Feminine Hygiene *Hy-Jet Wafers* \* \* \* buffered to maintain an acid condition in the vaginal mucosa \* \* \* Medco Company, Inc., New Orleans, Louisiana"; "100 Cotabs MEDCOL \* \* \* Each Cotab contains: Pyrilamine Maleate 4 mg., Metapyrilene HCl 4 mg. \* \* \* Caution:"; and "100 Tablets Medatinic 500 Mg. Each Tablet Contains: Nicotinic Acid 500 Mg. (Niacin) \* \* \* Mfg. for Medco Co., Inc., New Orleans, La."

**RESULTS OF INVESTIGATION:** Analysis of the *Hy-Jet Wafers* showed that they contained boric acid and phenylmercuric borate in an effervescent base. The other articles were assumed to contain the ingredients listed on their labels. The *Medcol Cotabs* and the *Medatinic tablets* contained in the bottles had been repacked by the dealer from bulk containers shipped as described above.

**LIBELED:** 5-24-61, E. Dist. La.

**CHARGE:** 502(a)—when shipped, the label of the *Hy-Jet Wafers* contained false and misleading representations that the article was adequate and effective for the treatment of monilia, trichomonas, staphylococcus, and streptococcus infections of the vaginal tract; and 503(b)(4)—while held for sale, the label of the *Medcol Cotabs* bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to 503(b)(1); and 503(b)(4)—while held for sale, the *Medatinic tablets* were a drug subject to 503(b)(1) and their label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** *Medcol Cotabs* and *Medatinic tablets*, 6-29-61. Consent—claimed by Medco Co., Inc., and released under bond for relabeling. *Hy-Jet Wafers*, 7-14-61. Default—destruction.

**6790. Vigosan tablets.** (F.D.C. No. 45898. S. Nos. 32-272/3 R, 32-283/4 R.)

**QUANTITY:** 323 25-tablet btls. and 78 50-tablet btls. at San Juan, P.R.

**SHIPPED:** 3-10-61 and 4-25-61, from New York, N.Y., by Gold Leaf Pharmacal Co., Inc.

**LABEL IN PART:** "Vigosan \* \* \* Gold Leaf Pharmacal Co., Inc., New Rochelle, N.Y. \* \* \* Each tablet contains: Testosterone 2 mgm. Yohimbine HCl. 5 mgm. Vitamin E 10 mgm. Extract Damiana 60 mgm. Extract Nux Vomica 5 mgm. Dosage: One or two tablets 3 times daily."